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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,614	01/22/2001	Jo Klaveness	REF/Klaveness/054C	9751

23364 7590 06/26/2003  
BACON & THOMAS, PLLC  
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ALEXANDRIA, VA 22314

EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/26/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/765,614	KLAVENESS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael G. Hartley	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38,40,41,47-49 and 63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38, 40, 41, 47-49 and 63 is/are <sup>rejected</sup> ~~allowed~~.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/05/2003 has been entered.

***Response to Amendment***

The amendment filed 05/05/2003 has been entered. Claims 42-44 have been canceled. Claim 38 has been amended.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38, 40, 41, 47-49 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,997,898) in view of Schneider (US 5,643,553) and Martin (US 5,891,468), for the reasons set forth in the office action mailed 7/09/2002.

Applicant's arguments filed 05/05/2003 have been fully considered but they are not persuasive.

Applicant asserts that Unger refers to the use of "fluorinated amphiphiles" and applicants have found that their agents do not have to be limited this way.

This is not found persuasive because the instant claims do not exclude the use of "fluorinated amphiphiles" as the claims recite "comprising" which is open-ended claim terminology. The claims only require the use of some named specific phospholipids which are included as the film-forming surfactants,

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and Unger discloses the use of the same film-forming phospholipid surfactants, such as, phosphatidylcholine, etc., see column 20, lines 18+.

Applicant asserts that Unger fails to disclose the use of one or more vectors, wherein said vectors bind to receptors/targets associated with angiogenesis, inflammation, atherosclerotic plaques and/or thrombi.

This is not found persuasive because the rejection is based on a combination of references. Unger discloses the same gas-filled microbubbles as claimed, which are used for diagnosis and/or therapy, and provides a general teaching that the microbubbles may include various vectors to target a desired site. Unger also teaches that the microbubbles may be used for treatment of atherosclerosis and cancer, see column 29, lines 23+. Schneider and Martin teach that similar vesicles may include targeting agents and that the targeting agents bind to the receptors/targets as claimed. For example, Schneider teaches that gas-filled microbubbles may include a vector to thrombi or atherosclerotic plaques, see column 9, lines 10+. While Martin teaches the use of various targeting agents, for inflammation, plaques, etc., including the use of applicant's elected species an anti-CD34. One of ordinary skill in the art would have been motivated to employ any known targeting agent for a desired site which are used in diagnostic and/or therapeutic agents that are analogous to those disclosed by Unger, given the teaching in Unger that various targeting agents may be employed. Schneider specifically teaches that ultrasound contrast agents should include a vector to thrombi or plaques. Martin teaches that therapeutic liposomes (e.g., which Unger also discloses), should include a targeting agent such as those encompassed by the claims.

Applicant asserts that Unger and Martin are not in the same field of endeavor.

This is not found persuasive because both Unger and Martin are in the same field of endeavor, which is the use of liposomes for therapy. Note that both patents have the same original classification, 424/450. One of ordinary skill in the art would have been motivated to consider all pertinent art in the field of therapeutic liposomes when performing endeavors in this field. Unger clearly discloses both diagnostic and therapeutic use of liposomes, see column 4, lines 40-52.

Applicant also asserts that Schneider relies on a different system and therefore is not in a relevant area of technology.

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This is not found persuasive because Unger and Schneider are clearly in the same field of endeavor, namely, gas-filled microbubbles for ultrasound contrast agents. Given that Schneider teaches that it is beneficial to employ a targeting agent that is specific for thrombi or plaques to improve the accumulation of such ultrasound contrast agents to this site to optimize ultrasound imaging thereof, one of ordinary skill in the art would have been motivated to use such a targeting agent as the targeting agent disclosed by Unger, which would arrive at the claimed invention.

Applicant asserts that Martin teaches various vectors and fails to provide a teaching to the group claimed.

This is not found persuasive because while Martin teaches various vectors, Martin teaches that various vectors, such as those claimed, can be used as equivalents to provide targeting to various sites, which include the broad group (genus) as claimed. Also, Schneider specifically teaches the desirability to target such sites in ultrasound imaging. Given that the art, as a whole, clearly teaches that targeting diagnostic and therapeutic microbubbles and/or liposomes to inflammation, plaques, thrombi, etc., one of ordinary skill in the art would have been motivated to use various known equivalents as the targeting agent in the microbubbles disclosed by Unger.

### **Conclusion**

No claims are allowed at this time.

This is a RCE of applicant's earlier Application No. 09/765,614. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action

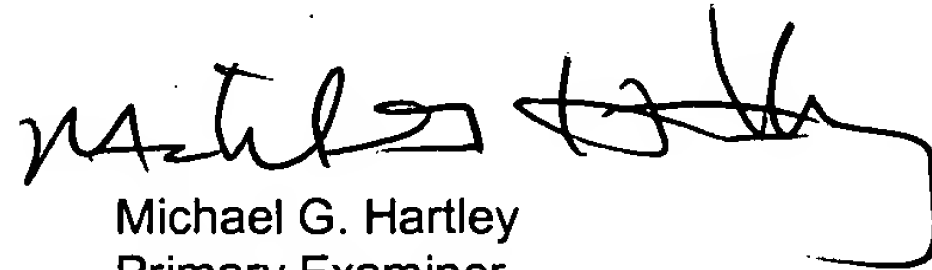
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is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Michael G. Hartley', with a stylized flourish extending from the end.

Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
June 24, 2003